Remarks

The office action has identified several deficiencies with respect to the filing of the present divisional reissue application, and the claims have been rejected under 35 U.S.C. §§112 and 102. Applicant herein submits its response.

The office action notes that this reissue application is required to include a reference to all of the reissue cases, and this has been done by the amendment to the specification. The reissue application has also been indicated as requiring an assent of the assignee and a sufficient oath/declaration, and applicant is obtaining both of these items and will submit them in a supplemental response to the office action. The previous amendments to the claims have also been indicated to be in an improper form, and applicant has submitted new claim amendments which are believed to be in proper form, including underlining of all claims in their entirety.

Claims 39-67 were previously in the application, and the cancellation of those claims obviates the previous rejections. New claims 68-104 have been added by this Amendment, and the previous rejections will be addressed with respect to these new claims.

Claims 39-59, 61-64 and 66-67 were rejected under §112. Without conceding the bases for the rejections, it is noted that those claims have been cancelled and the rejection is thereby obviated. In further response, applicant submits the following. All of the current claims relate specifically to an electrochemical test strip including working and counter electrodes and a reagent. The claims also provide more particular detail as to the configuration of the test strip and the included "fill line." Applicant believes that the new claims are sufficient under §112.

The cancelled claims were also previously rejected under §102 on the basis of several cited patent references. The cancellation of those claims has obviated these rejections. New claims have been submitted in an effort to further focus the examination of this application. Applicant will comment on the cited patents in respect to new claims 68-104.

Support for New Claims 68-104

The new claims 68-104 are clearly supported in the original specification of this application. These claims generally relate to electrochemical test strips which provide a means for the user to visually monitor the capillary flow of blood into the test strip at least up to a fill line. The user is able to visually confirm that a sufficient amount of blood has been received in the test strip in order to conduct an accurate glucose test by observing the flow of the blood sample to the fill line.

General support for the new claims is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly Figures 1, 3i and 5), and the disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. In addition to these general portions of the specification, support for the claims can be found as follows:

General claim features:	Support:
a strip body defining a capillary channel, a vent in fluid communication with the capillary channel, a sample application port open along the edge, the capillary channel extending from the sample application port to at least the vent	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge	Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least at the working electrode	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to those exposed surfaces of tracks 5 and 6."
visualization means enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, including a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including the working electrode and at least a portion of said counter electrode	Abstract, lines 11-15: ". . . identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 36-36: "Further, insufficient sample may also be drawn into the capillary reaction chamber, thereby resulting in an inaccurate test result." Col. 1, line 60 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
strip body including opposed sides of the capillary channel, the sides being parallel and extending in a straight	See Figures 3i and 5. Also see:

line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes, the fill line extending orthogonal to the channel sides	Col. 8, lines 26-31: "The window is positioned and dimensioned so that when the roof is affixed to surface 8, it will align with opening 11 as shown in FIG. 3h." Col. 8, line 52 to col. 9, line 9: "Finally, roof 13 is placed onto surface 8. (See FIG. 3h) It is at this stage that the transparent or translucent window 18 defined by the absence of printed ink on roof 13 must align with opening 11 as shown in FIG. 3h." Figures 3h and 31.
strip body including opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes	Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
opaque portions spaced apart to reveal greater than about 75% of the width of the capillary channel	Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18.
strip body includes a first substrate, a second substrate and a roof, the second substrate positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
test strip includes conductive tracks connected with the working and counter electrodes, the first substrate affixed to the second substrate to expose a portion of the conductive tracks for electrical connection to a meter, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode	See claim 104 and the Figures.

As a preliminary comment, applicant notes that all of the devices described in the cited patent references are distinguishable from the present invention in the respect that they fail to disclose or suggest a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be visualized to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate. Electrochemical test strips are unique as compared to test strips involving color change, fluorescence or other reaction indicators involving direct viewing of the test site. Those test strips naturally have an area for visualizing the test area because the results are detected in that manner. Such test devices will therefore provide some amount of visibility to the test area.

The present claims are limited, however, to capillary-fill devices in which a transparent or translucent portion overlies the internal capillary chamber. Moreover, this transparent or translucent portion is indicated to be a "solid" material. The claims are therefore specifically distinguished from prior art devices in which there is simply an opening that is exposed to the outside without a solid material providing visualization of a blood sample as it fills into the interior capillary chamber.

The Diebold et al. patent 5,437,999 has been cited for showing a device with cut out portions, a vent and reagents associated with the electrodes. However, there is no teaching of a test strip which has a solid, transparent or translucent portion overlying the capillary chamber, nor is there a suggestion for a fill line used in conjunction with such a solid portion.

Gin et al. patent 5,006,310 and Nagase et al. patent 5,170,799 have been cited as teaching test devices for the collection of tear fluids which include a notch adjacent to the sample collection area. However, the Gin et al. patent does not even include drawings, and

Nagase et al. only disclose a foldable test strip made from filter paper or the like. Neither patent discloses a solid, transparent or translucent portion for tracking the progress of a blood sample moving by capillary action to a fill line.

The Poto et al. patent 5,728,352 has been cited as teaching test strips having a sample application port and an angled tab. However, Poto is typical of the "top dosing" prior art test strips in which the blood sample is applied directly to the planar surface of the test area. There is no capillary filling of the test strip, and therefore there is no need (or opportunity) to view the filling of the test strip through a solid, transparent or translucent portion to ensure that a sufficient amount of blood has reached the test area. In contrast, the present invention specifically addresses capillary-fill electrochemical test strips, where problems of inadequate dosing of blood can lead to erroneous results because there is insufficient blood covering the reagent and the working/counter electrodes.

Galen et al. 6,027,692 has been cited for teaching a test strip having a sample application port along an edge for assuring proper alignment with a detector. However, it again is a top-dosing strip with openings 6, 7 and 11 extending from the top substrate through to the bottom substrate. There is no solid, transparent or translucent portion to allow blood to be visualized, and no fill line to indicate when sufficient filling has occurred.

The Charlton et al. patent 5,798,031, Seshimoto et al. patent 4,684,445, Columbus patent 4,473,457 and Ikeda et al. patent (for which applicant believes the proper number is 5,575,895) have all been cited as teaching electrochemical test devices with transparent and opaque portions, a conductive track, vents, and a sample application port. Applicant submits, however, that new claims 68-104 are readily distinguished from these references for the same reasons as indicated for the other prior art. The Charlton patent shows a test strip having a

base 36 and a lid 46, with the lid being embossed to form a concave space 48 to receive a blood sample. But Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent, and does not identify a fill lineSeshimoto et al., Columbus, and Ikeda similarly fail to show solid, transparent or translucent portions and associated fill lines, but rather have open portions and/or interior portions not viewable from externally of the device.

In addition to the cited art, applicant has previously submitted an Information Disclosure Statement in this application identifying a prior art device marketed by Bayer Corporation under the trademark GLUCOMETER ELITE®.

The Glucomete Elite product is an electrochemical test strip including a pair of electrodes received at the end of a capillary channel, which channel extends to the electrodes from a sample application port at the perimetric edge of the test strip. The Elite device includes several layers, including a spacer and a top cover. It appears clear that the spacer and top cover are both transparent materials, as the components underneath these layers are visible. The Glucometer Elite product would apparently allow the viewing of a blood sample as it enters the capillary channel, but it does not provide a fill line indicating the distance which the blood sample must reach for conducting an accurate test. A person could therefore see blood enter the strip and conduct a test, and yet obtain inaccurate results if the blood did not sufficiently fill the capillary chamber. Further, the Glucometer Elite test strip does not include opaque portions which distinguish the capillary fill channel from other parts of the test strip. Thus, when blood is dosed to the Glucometer Elite strip, the user would be able to see blood moving into the strip, but would not be able to tell if it was filling the capillary channel or some lesser portion of the interior of the strip.

The present invention is therefore seen to be uniquely distinguished from the above-described prior art. Reconsideration of the application and allowance of new claims 68-104 is therefore respectfully requested. The examiner is requested to contact the undersigned by telephone if it appears that issues may be more readily resolved leading to allowance of this application.

Respectfully submitted,

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